IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: MARSHALL, WILLIAM E.)
) APPEAL NO
SERIAL NO: 09/883,550)
FOR: METHODS AND COMPOSITIONS FOR MODULATING IMMUNE SYSTEMS OF ANIMALS)) BRIEF ON APPEAL)
FILED: JUNE 18, 2001)
)
GROUP ART UNIT: 1638))
To Commissioner for Patents Mail Stop Appeal Brief – Patents P.O. Box 1450 Alexandria, VA 22313-1450	
Dear Sirs and Madams:	
In response to the Notification of Non-Co	ompliant Appeal Brief dated March 1,
2007, please find attached Section VIII Claims A	appendix. Applicants believe that they
are in compliance with 37 CFR 41.37(c)(1)(v) and	nd request that this be entered.
CERTIFICATE OF MAILING	G/TRANSMISSION
I hereby certify that this correspondence is, on the date sho	own below, being:
Service with sufficient postage as Express mail in an envelope addressed to the Commissioner for Patents, Mail Stop BPAI - Supplemental Appeal Brief	ELECTRONIC I transmitted by electronic to the Patent and Trademark Office, using the EFS
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Date: 3-15-07	JANAE E. LEHMAN BELL, Ph.D.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

- 1. A method for modulating the immune system of an animal comprising: growing bacteria in a medium;
- exposing said bacteria to biological, chemical or physical stress for at least two or more sequential periods of stress wherein each period of stress is defined by a period of stress exposure of approximately 20 minutes or less so that the bacteria release a stress response product comprising stress response factors (SRFs);

separating said medium and SRFs from said bacteria to form a separated product; filtering said separated product to remove substances having a molecular weight of greater than 10kDa to form a filtrate; and administering said filtrate to said animal.

- 4. The method of claim 1 wherein said medium comprises a non-nutritive saline media at pH values of 6.0 to 8.0.
- 5. The method of claim 4 wherein said saline media is a phosphate-buffered saline having a pH of about 7.0.
- 6. The method of claim 1 wherein the bacteria are selected from the group consisting of Lactobacillus, Staphylococcus, Streptococcus, Pediococcus, Pseudomonas, Bacillus, Escherichia, Listeria, Enterococcus, and Klebsiella.
- 7. The method of claim 6 wherein the bacteria are selected from the group consisting of *L. acidophilus*, *L. caseii*, *L. fermentum*, *L. plantarum*, *L. monocytogenes*, *S. aureus*, *S. typhimurium*, *P. acidolactici*, *B. coryneforme*, *E. coli*, *E. faecium*, *S. pyogenes*, and *K. pneumoniae*.
- 8. The method of claim 1 wherein the bacteria are propagated at a temperature ranging from approximately 22°C to approximately 37°C.

- 10. The method of claim 1 wherein the bacteria are exposed to a stress while they are in the stationary phase of their life cycle.
- 11. The method of claim 1 wherein the filtering step includes: passing said separated product through a 0.22 µm filter to form a sterilized product; and passing said sterilized product through a filter with a molecular weight cutoff of 10 kDa.
- 12. The method of claim 1 wherein the filtrate containing the stress response factors (SRFs) with a molecular weight less than 10kDa is administered to an animal selected from the group consisting of humans, poultry and livestock.
- 14. The method of claim 1 wherein the stress response product is administered in a manner selected from the group consisting of orally, topically, and parenterally.
- 15. The method of claim 1 wherein the animal is administered stress response products having a weight of between 0.5 and 3 kDa.
- 16. The method of claim 1 wherein the stress response products are administered as an adjuvant for oral or parenteral vaccines.
- 17. The method of claim 1 wherein the bacteria are exposed to at least two or more sequential periods of stress wherein each period of stress is approximately 10-20 minutes.
- 18. The method of claim 17 wherein the bacteria are exposed to sequential periods of stress by transferring the bacteria from growth media into non-nutritive media in the initial period of stress, then subsequently transferring the bacteria to non-nutritive media in the sequential periods of stress.
- 19. The method of claim 18 wherein the bacteria are exposed to three sequential periods of stress.